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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/629,242	07/31/2000	Benjamin D. Pless	473912000100	3876
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MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3739	PAPER NUMBER
DATE MAILED: 11/07/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/629,242

Applicant(s)

PLESS, BENJAMIN D.

Examiner

Henry M Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments, see page 2, filed 7/28/2003, with respect to claim 11 have been fully considered and are persuasive. The rejection under 35 USC §112 of claim has been withdrawn.

Applicant's arguments with respect to art rejections of claims 1 and 11 have been considered and are not persuasive. Further, new ground(s) of rejection are cited. The pattern of the lesions in photodynamic therapy is directly related to the pattern of the light source. Any method for producing lesions using photodynamic therapy and a patterned light source will produce a lesion pattern corresponding to the light source pattern.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,143,019 to Motamedi et al. Motamedi et al teaches a method for cardiac tissue ablation (lesion) using light activated substances with photodynamic therapy (Col. 6, lines 3-7) for modification of tissues responsible for cardiac arrhythmias (abstract). Photodynamic procedures inherently use non-thermal light in the process. All light sources, including a single source, produce light in a predetermined pattern that will produce a predetermined result on sensitized tissue. The lesion pattern is inextricably related to the light pattern. An ectopic focus

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focus associated with a ventricle tachycardia is disclosed as a specific type of arrhythmia implying the treatment of that condition.

Claims 1-5, 11-14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Publication 2002/0095197 to Lardo et al. Lardo teaches a non-thermal method for the treatment of cardiac arrhythmia (Paragraph 0011) using a photosensitizing agent (Paragraph 0012) and illumination by a fiber-optic catheter that may be arranged in a linear or ring shaped pattern (Paragraph 0015) to produce well-defined patterns of cardiac ablation (Paragraph 0035). Lardo teaches the ectopic foci of the pulmonary veins as target areas (Paragraph 0007). The photosensitizing agent may be delivered systemically or locally (Paragraph 0016).

Claims 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,443,974 to Oron et al. Oron discloses a catheter for biostimulation of cardiac tissue using electromagnetic radiation that may be visible light (abstract). The light emitting area is disclosed as being flexible with the radiating element in a cutaway section (window) and a lens for emitting the beam in an outward radial direction (Col. 22, lines 42-52). The radiating area is surrounded by the catheter body (opaque) and is linear for a length of 2-3 cm (Col. 22, line 56). The radiating area inherently emits substantially all of the light from the device due to the catheter body blocking radiation in other directions and a reflecting coating on the inner surface (Col. 22, line 53). In response to applicant's argument that "lesions are not disclosed", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result

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in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-10 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication 2002/0095197 to Lardo et al as applied to claims 1 and 11 and further in view of U.S. Patent 6,164,283 to Lesh. Lardo discloses photodynamic therapy for treating cardiac arrhythmias as an alternative to the more common radio frequency ablation (Background of Invention), but fails to disclose specific treatment areas. Lesh teaches methods to electrically isolate specific areas of the heart using ablative means to treat arrhythmia. Both interrupt the cardiac electrical process by ablating (creating lesions). This establishes the PDT technique as an alternative equivalent to RF ablation for interrupting this activity. Lesh teaches that focal arrhythmia often originate from a tissue region along the pulmonary veins of the left atrium, and even more particularly in the superior pulmonary veins. The method of treating involves forming a circumferential conduction block, using an internal catheter with ablation means, which is located either (a) along a circumferential path of tissue in a pulmonary vein wall which circumscribes the pulmonary vein lumen and transects the electrical conductivity of the pulmonary vein relative to its longitudinal axis, or (b) along a circumferential path of tissue in a left posterior atrial wall which surrounds a pulmonary vein ostium and electrically isolates the pulmonary vein and the ostium from a substantial portion of the left posterior atrial wall including the other of the vein ostia. Lesh further teaches an external procedure wherein a

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circumferential conduction block of one or more pulmonary veins may be performed in an epicardial ablation procedure, wherein an ablation element is either placed around the target pulmonary vein or is translated circumferentially around it while being energized to ablate the adjacent tissue in an "outside-in" approach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the photodynamic techniques of Lardo as an alternative equivalent to the RF ablative methods for treating cardiac arrhythmias in the patterns and areas as taught by Lesh.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,443,974 to Oron et al. Oron is discussed above but does not disclose LED's as a light source. The use of LED's is well known in the art and therefore it would have been obvious to use LED's in the device of Oron as a viable light source.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Henry M Johnson, III
Patent Examiner
Art Unit 3739

Hmj



Lee Cohen
Primary Examiner